# PATENT COOPERATION TREATY



From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

A.P.T. Patent and Trade Mark Attorneys
PO Box 222
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# PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

| | |
|---|---|
| Date of mailing *(day/month/year)* | 17 MAY 2004 |
| Applicant's or agent's file reference<br>2676pct:PJW:AML | FOR FURTHER ACTION<br>See paragraph 2 below |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/AU2004/000416 | 29 March 2004 | 28 March 2003 |

International Patent Classification (IPC) or both national classification and IPC
**Int. Cl.**[7] C12N 5/00, 5/08

Applicant
MEDVET SCIENCE PTY LTD et al

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [X] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No.

**PCT/AU2004/000416**

**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ in written format

      ☐ in computer readable form

   c. time of filing/furnishing

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
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International application No.
PCT/AU2004/000416

**Box No. V** **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 49 | YES |
| | Claims | 1-48, 50-67 | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 1-67 | NO |
| Industrial applicability (IA) | Claims | 1-67 | YES |
| | Claims | | NO |

2. Citations and explanations:

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1. WO 2001/004268 A1 MEDVET SCIENCE PTY LTD (18 January 2001)

D2. SHI, S. et al (2001) "Comparison of Human Dental Pulp and Bone Marrow Stromal Stem Cells by cDNA Microarray Analysis" *Bone*, 29(6):532-539.

D3. JONES, E. A. et al (2002) "Isolation and Characterization of Bone Marrow Multipotential Mesenchymal Progenitor Cells" *Arthritis & Rheumatism*, 46(12):3349-60.

D4 GRONTHOS, S. et al (2002) "Stem Cell Properties of Human Dental Pulp Stem Cells" *J. Dent. Res.*, 81(8):531-535.

Novelty (N) and Inventive Step (IS)

D1 teaches a method of enriching mesenchymal precursor cells (MPC) using STRO-1 along with VCAM1, ICAM1, THY-1, CD49/CD29, CD29, Cd61, thrombomodulin, CD10, CD14 and SCF amongst others. D1 also teaches that the cells are +glycophorinA. Since the methods enrich for cells and cell compositions positive for the above, they are prejudicial to the novelty of claims 1-8, 10-13, 15-23, 25-48 and 50-67 that define methods for enriching, cells and compositions comprising various combinations of these markers. It is noted that this citation does not disclose the surface marker 3G5. However, given that the cells of this citation disclose a good proportion of the markers used to enrich for the cells of the present application, it is most likely that 3G5 is, in fact, expressed by the cells of the citation. Merely identifying further characterising features of a known cell does not impart any novelty on that cell.

D2 through D4 all disclose cells that contain various combinations of the surface markers of the present invention that appear to fall within the scope of the claimed cells. They too, do not disclose all of the markers, however there is no evidence to suggest that these markers are not inherently contained on these cells. Thus, as with D1, merely identifying further characterising features of a known cell does not impart any novelty on those cells. Therefore, D2-D4 are novelty destroying for the cells of claims 1-39.

Any one of D2-D4, or D2-D4 combined, provide the person skilled in the art with the means and impetus to make use of the disclosed surface markers to enrich for MPCs. The person skilled in the art is also keen to analyse any cells so enriched for further enrichment mechanisms and would thus be led to find further surface markers of interest and to continue to refine the enrichment process. Given that the surface markers of the cells are considered an inherent feature of the disclosed cells, it would be expected that the person skilled in the art would have found and made use of these thus identifying the surface markers of the invention. Thus, without any evidence or a surprising result or technical difficulty overcome, none of the method claims 40-67 can be considered inventive in light of these documents either singly or together.

**WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY**

International application No.

**PCT/AU2004/000416**

**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 11-21, 24-41, 43-46, 48-56, 58-67 are not adequately supported by the description. The description provides that an enriched population of MPCs can be differentiated into two populations discriminated by the marker 3G5 and that those cells +3G5 are considered of interest for neovascularization applications. The key element in this enrichment and all subsequent use is thus the 3G5 surface marker. These claims are not limited to either cells +3G5 or for methods making use of 3G5 and thus they do not enjoy full support from the description.